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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/469,733	12/21/1999	JEFFREY B. ETTER	42830-00060	5320

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/19/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/469,733	Applicant(s) ETTER, JEFFREY B.	
	Examiner Samuel W Liu	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) none is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input checked="" type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>9</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

The rejection of Claims 1-48 under 35 USC § 112 first paragraph on the basis of the amendments and applicant's comments in the response filed 12 march 2002 is withdrawn.

The Response filed on March 12, 2002 (paper 11) has been received and entered. Amendments of Claims 1, 14, 18, 23, 35, 38, 46 and 47 and the extension for three months have been entered. Claims 1-48 are pending to which the followings are or remain applicable.

Specification/ Objections

The disclosure is objected to because of the following informalities:

- (1) In page 17, line 16, "phosphozene" should be changed to "phosphazene".
- (2) All numbers referring to Figure 1, 102, 104, 106, 108, 110, 112 and 114 throughout the specification are advised to be parenthesized in order for clarity.
- (3) In page 9, line 6-10, the recitation "the resulting mixture 108 of process fluid and ..." is unclear and inconsistent with what is described in "brief description of the drawings" referring to Figure 1.

Correction is required.

Drawing

The drawing (Figure 1 and 3) filed on December 21, 1999 is acceptable subject to correction of the informalities indicated on the attached "Notice of Draftperson's Patent Drawing Review," PTO-948. In order to avoid abandonment of this application, correction is required in reply to the Office action. The correction will not be held in abeyance.

The following is the information on how to effect drawing changes.

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1. New corrected drawings must be filed with the changes incorporated therein.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948. All changes to the drawings, other than informalities noted by the Draftsperson, MUST be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings MUST be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

In addition, Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in abandonment of the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the claim recites “the cosolvent system including at least a first organic solvent and second organic solvent, ...”. The recitation “cosolvent system ... at least “ appears to encompass any organic compounds that are polar, partial polar, non-polar and partial nonpolar, polymers that are polar, partial polar, non-polar and partial nonpolar, even those such as any chiral molecules and chiral aggregates. Applicant asserts that the “cosolvent system” is not indefinite because the system includes at least two organic solvents. Here, “at least” is open and sets up an unlimited range of compositions of said system; it encompasses a variety of ratios of good/poor solvents apart from the said two organic solvents; thus, the language renders the claim indefinite. Also, the response (Page 3, paragraph 4) argues that the specification has thoroughly discussed cosolvent system; however, in page 4, lines 17-19, the response recites “The cosolvent system includes at least a first organic solvent and a second organic solvent, although *additional* organic solvents may be included as described for a *particular* application”. What is the particular application? In view of this recitation, it does not exclude any additional organic solvents and render the system “open” such that the cosolvent system would include any unanticipated and undefined compositions. Thus, the claim is indefinite as to what additional items are included.

Claim 1 is also grammatically awkward as to “...making an insulin-containing particulate product...” because it is unclear as to the question: does the insulin contain the

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product as recited or does the product contain insulin? See "... an insulin-containing particular product,..." in the claim. For clarity, please use "contacting a feed solution containing insulin (Claim 1, line 2) and "to precipitate particles containing insulin" (Claim 1, line 3-4). Also, in Claim 47, the recitation "the the" is either awkward or there are missing the terms between "the the".

In claim 2, the term "at least about", in claims 3, 10, 11, 15, 36 and 39-41, the term "larger than about" and in Claims 5 and 17, the term "smaller than about" are all indefinite because "at least", "larger than", and "smaller than" mean that the value cannot go below or above a stated number; but by use of "about" it is permissible. Which term is limiting? Is it the about, or the at least, or the larger than, or the smaller than? Please use one or the other but not (i) both the about and the at least, (ii) both the about and the larger than, and (iii) both the about and the smaller than together. See all claims which have similar terminology, e.g. claims 10, 11, 15 and 17, as well as Claims 46 and 47 which recite "greater than about".

In Claim 6, the commonly accepted notation for milliliter is "ml", not "mL".

In Claim 7, the "DMSO" and "DMSF" should be spelled out prior to first use in claims. The same is Claim 24; the "THF" needs to be spelled out in full.

Claim 19 is indefinite as to how much is "a portion" recited in the claim.

There are other open language, e.g. "at least" (Claim 1, 24 and 27). In Claims 1 and 19, recitation "at least" renders the claims indefinite as to unpredictably additional third solvent that might be employed in Claim 1. The claim terminology of "at least" in Claim 24 is indefinite since it is not apparent what one(s) or more of the list solvents are permissible in the claim as a

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combination and what the amounts of each in the combination(s) would have been. The same reason is applicable to Claim 27 which recites "at least". Are there combinations of using methanol and ethanol or isopropanol and so on?

Claim 20 is indefinite as to not clearly stating the components of the particles. The claim recites "wherein ...the insulin-containing particles comprise multiple-component particles including insulin and the biocompatible polymer". Do the insulin-containing particles contain biocompatible polymer or not? It is unclear about connection with the particles.

The recitation "greater than" in Claims 46-47 is unclear as to absence of limitation to polymer percentage which determines a degree of encapsulation of the insulin so that it would result in any percent amount more than 50% or 70 %, even more than 100% and so on; thus, the term "greater than" renders the claims indefinite. See also "larger than about" in Claims 3, 10, 11, 15, 36, 39 and 41 and the term "smaller than" in Claim 5.

Claims 4, 6, 16, 37 and 45 are indefinite because of the type of the recitation "...from about ... to about ..."; it is ambiguous regarding what are encompassed in this limitation. The recitations appear to set " \pm " parameter on both ends of the range comprising: a) volume ratios of the second organic solvent to the first organic solvent (Claim 4), b) the concentration of insulin in the cosolvent system (Claim 6), c) direction angles for applying the feed solution into the compressed anti-solvent fluid (Claim 16), and d) weight ratios of the insulin to the polymer in the feed solution (Claim 37), respectively. It therefore would result in a vague and unpredictable range for using claimed compositions.

The response filed 12 March 2002 at page 3-6 discusses the amended claims and why they are not indefinite. The comments are unpersuasive. At page 3, the issue of open-ended

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language is discussed but is unpersuasive because even where currently amended, the claims are indefinite for the reasons stated in the above ground of rejection.

In page 3-5, applicant asserts unawareness of many open-ended terms and arguments toward the examiner's objections (see page 3, paragraph 3, page 4, the last paragraph, and page 5, paragraphs 1-6). In the instant application, there are open-ended terms e.g. "larger than about" (Claims 3, 10, 11, 15, 36 and 39-41), "at least about" (Claim 2), similar terminology "smaller than about" (see Claims 5 and 17), "greater than about" (see Claims 46-47), "from about ... to about ..." (see Claims 4, 6, 16 and 37), and "at least" (see Claims 1, 19, 24 and 27). For the details, please see the above stated ground of rejection under 35 U.S.C. 112 first paragraph.

Remark

Applicants' comments in the response as to the 35 U.S.C. 112 second paragraph rejection have been considered but they are unpersuasive for the reasons stated in the ground rejection.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483.

The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 703 308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this

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application or proceeding should be directed to the receptionist whose telephone number is 703
305-4700.

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April 18, 2002

Christopher S. F. Low
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